

# MEASUREMENT OF EFFECTIVENESS AND OUTCOMES IN HEALTH CARE

## HEALTH SERVICES 214

WINTER, 2003

William E. Cunningham, M.D., M.P.H. and Ron D. Hays, Ph.D.

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Time and Place: Mondays, 9:00 a.m. – 11:50 a.m., Room. 61-262 CHS

Required readings: Course syllabus (Reader at Course Reader Material, 310.443.3303)

Useful Texts (On Reserve in the Biomedical Library):

Bowling, A. Measuring Health: a review of quality of life instrument scales. 1997 Milton Keynes: Open University press.

Kane RL. Understanding Health Care Outcomes Research. 1997, Aspen Publishers, Inc.

McDowell I, Newell C. Measuring Health, 2<sup>nd</sup> Edition, 1996, New York: Oxford University Press

Patrick DL, Erickson P. Health Status and Health Policy: Quality Life in Health Care Evaluation and Resource Allocation, 1993, New York: Oxford University Press.

Spilker B (ed). Quality of Life and Pharmacoeconomics in Clinical Trials. 2<sup>nd</sup> edition, 1996, Lippincott-Raven Publishers, Philadelphia, PA.

Staquet M, Hays R, & Fayers P. (eds.), Quality of Life Assessment in Clinical Trials: Methods and Practice, 1998, Oxford: Oxford University Press.

Stewart AL, Ware JE Jr. Measuring Functioning and Well-being, The Medical Outcomes Study Approach, 1992, Durham and London: Duke University Press

Wilkin D, Hallam L, Doggett MA. Measures of Need and Outcome for Primary Health Care, 1992, New York: Oxford University Press.

Additional readings listed in syllabus:

Because of the expense of publication, the additional readings (references) for each session are not included in the course reader; however, the full citations are provided.

Course objectives:

This course will provide a broad perspective on the conceptualization and development of health-related quality of life and their application to the assessment of outcomes and effectiveness in medical care. The focus is on the links between theory, methods, and practical applications. Representative state-of-the-art methods will be reviewed and placed in the context of current health service research practice. By the end of the course students will be familiar with a variety of approaches to health status assessment and should have a framework and specific skills for determining how and when health status assessment should be incorporated into health services research programs.

**Reading assignments are to be done before class.**

- **5-MINUTE SUMMARY OF REQUIRED READING EACH WEEK, RANDOMLY ASSIGNED STARTING WEEK 2**
- **ABSTRACT OF FINAL PAPER TOPIC DUE FEB. 10, 2003**
- **FINAL PAPER (research proposal) DUE MARCH 14, 2003**

Evaluation of Student Performance:

Class participation	30%
Term Paper	70%

MEASUREMENT OF EFFECTIVENESS AND OUTCOMES IN HEALTH CARE

HEALTH SERVICES 214

Winter, 2003

Lectures Schedule

WEEK	DATE	TOPIC	LECTURER
1	January 6	Importance of Health-Related Quality of Life ..... Introduction to Measures	Cunningham ..... Cunningham
2	January 13	Generic and Targeted Profile HRQOL Measures	Hays
3	<b>January 20</b>	<b>Holiday</b>	
4	January 27	Reliability, Validity, and Acceptability, PART I ..... Reliability, Validity, and Acceptability, PART II	Cunningham ..... Hays
5	February 3	Selecting HRQOL Measures for Outcomes Studies ..... Liver Disease and HRQOL	Cunningham ..... Ian Gralnek
6	February 10	Prostate Cancer and HRQOL ..... Neurologic Disease and HRQOL	Mark Litwin ..... Barbara Vickrey
7	<b>February 17</b>	<b>Holiday</b>	
8	February 24	HRQOL Preference Measures ..... HRQOL in HIV/AIDS and HRQOL	Hays ..... Cunningham
9	March 3	Minimally Important Differences/Responsiveness to Change ..... Cancer, Lung Cancer, and HRQOL	Hays ..... Linda Sarna
10	March 10	Applicability of Generic Measures to Persons with Disabilities ..... Outcomes and Effectiveness Research in HIV/AIDS	Hays ..... Cunningham
11	March 14	Final Exams / Papers Due (Friday before Final exams week)	

**MEASUREMENT OF EFFECTIVENESS AND OUTCOMES IN HEALTH CARE**  
**HEALTH SERVICES 214**  
**Winter, 2003**  
**Reading Schedule**

**January 6, 2003 (Week 1)**

**A: Importance of health-related quality of life (Cunningham)**

**B: Introduction to measures (Cunningham)**

**Required Readings**

Wilkin, pp. 1-16.

Reiser S. The era of the patient: Using the experience of illness in shaping the missions of health care. JAMA 1993; 269:1012-1017.

Guyatt GH, Feeny DH, Patrick DL. Measuring Health-related Quality of Life. Ann Int Med. 1993;118:622-629.

**References:**

- Bergner M, Bobbitt RA, Kressel S, et al. The Sickness Impact Profile: conceptual formulation and methodology for the development of a health status measure. International Journal of Health Services 1976;6:393-415.
- Breslow L. A quantitative approach to the World Health Organization definition of health: Physical, Mental and Social Well-being. Int J Epid 1972; 1:347-355.
- Guadagnoli E and McNeil BJ. Outcomes research: Hope for future or the latest rage? Inquiry 1994; 31:14-24.
- Patrick DL, Bush JW, Chen MM. Toward an operational definition of health. Journal of health and social behavior 1973; 14:6-23.
- Spilker B. Quality of Life and Pharmacoeconomics in Clinical Trials. 1996. 2<sup>nd</sup> Edition. Lippincott-Raven Publishers, Philadelphia, PA. Introduction pgs 1-10.
- *Supplement* to Medical Care Journal (Special Issue). 2000;38(9).
- Ware JE Jr., Brook RH, Davies AR, Lohr KN. Choosing measures of health status for individuals in general populations. Am J Public Health 1981; 620-635.
- Ware JE. Conceptualizing disease impact and treatment outcomes. Cancer 1984;53S:2316-2323.

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**January 13, 2003 (Week 2)**

**Generic and Targeted Profile HRQOL Measures (Hays)**

Required Readings

Kane 1-28; 53-65.

Coons SJ, Rao S, Keininger DL, Hays RD. A comparative review of generic quality of life instruments. *Pharmacoeconomics* 2000; 17: 13-35.

References

- Patrick D, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Medical care* 1989; 27(3):S217-233.
- Stewart AL, Hays RD, Ware JE. The MOS short-form General Health Survey (SF-20). Reliability and validity in a patient population. *Medical Care* 1988;26:724-735.  
Stewart AL Greenfield S, Hays RD, et al. Functional status and well-being of patients with chronic conditions. *JAMA* 1989;262:907-913.
- Vickery BG, Hays RD, Genovese BJ, Myers LW and Ellison GW. Comparison of a generic to disease-targeted health-related quality-of-life measures for multiple sclerosis. *Journal of Clinical Epidemiology*. 1997; 50(5):557-569.
- Ware JE and Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): conceptual framework and item selection. *Medical Care* 1992;30:473-483.

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**January 20, 2003 (Holiday, Week 3)**

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**January 27, 2003 (Week 4)**

**A: Reliability, Validity, and Acceptability, Part I (Cunningham)**

**B: Reliability, Validity, and Acceptability, Part II (Cunningham)**

Required Readings

Dawes RM. Supposed we measured height with rating scales instead of rulers. *App Psy Meas*. 1977;2:267-273.

Kane, pp 219-233.

Hays RD, Anderson RT; Revicki D. Assessing reliability and validity of measurement in clinical trials. In M. Staquet, Hays R, and Fayers P, eds. Quality of Life Assessment in Clinical Trials: Methods and Practice Oxford: Oxford University Press. 1998. Chapter 10, pgs. 169-182.

## References

- Cunningham WE, Hays RD, Burton TM and Kington RS. Health status measurement and health status differences by age, ethnicity, and gender: Assessment in the Medical Outcomes Study. *Journal of Health Care for the Poor and Underserved*. 2000;11:58-76.
- Hays RD, Hayashi T. Beyond internal consistency reliability: Rationale and user's guide for Multitait Analysis Program on the microcomputer. *Behavior Research Methods, In*. 1990; 22(2) 167-175.
- Juniper EF, Guyatt GH, Jaeschke R. How to develop and validate a new health-related quality of life instrument. in *Quality of Life and Pharmacoeconomics in Clinical Trials*. 2<sup>nd</sup> Edition, B. Spilker ed. Lippincott-Raven Publishers, Philadelphia, PA. 1996., Chapter 6, pgs 49-56.
- McHorney CA, Ware JE, Razcek AE. The MOS 36-Item Short-Form Health Survey (SF-36): Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical Care* 1993; 31(3): 247-263.
- McHorney, C.A., Ware, Jr., J.E., Lu, J.F.R., and Sherbourne, C.D. The MOS 36-item short-form health survey (SF-36): III. Tests of data quality, scaling assumptions, and validity among diverse patient groups. *Medical Care* 1994; 32(1), 40-66.
- Sherbourne, C. D. and L. S. Meredith. Quality of self-report data: a comparison of older and younger chronically ill patients. *Journal of Gerontology* 1992; 47(4):S204-S211.

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## **February 3 (Week 5):**

### **A: Selecting HRQOL Measures for Outcomes Studies (Cunningham)**

### **B: Liver Disease and HRQOL (Gralnek)**

#### Required Readings

##### *Part A:*

Kane, pp 28-48, and pp 93-123.

##### *Part B:*

Gralnek, I. M.; Hays, R. D.; Kilbourne, A.; Rosen, H. R.; Keeffe, E. B.; Artinian, L.; Kim, S.; Lazarovici, D.; Jensen, D. M.; Busuttil, R. W., and Martin, P. Development and evaluation of the Liver Disease Quality of Life instrument in persons with advanced, chronic liver disease--the LDQOL 1.0. *Am J Gastroenterol*. 2000 Dec; 95(12):3552-65.

#### References:

##### *Part A:*

- Brook RH, Ware JE Jr., Roger WH, et al. Does free care improve adults' health? Results from a randomized controlled trial. *NEJM* 1983;309:1429-34.
- Stewart AL, Greenfield S, Hays RD, et al. Functional status and well-being of patients with chronic

conditions. Results from the Medical Outcomes Study. JAMA. 1989;262:925-930.

- Tarlov AR, Ware JE Jr., Greenfield S, et al. The Medical Outcomes Study. An application of methods for monitoring the results of medical care JAMA 1989; 262:925-930.
- Wells KB, Stewart A, Hays RD, et al. The functioning and well-being of depressed patients. Results from the Medical Outcomes Study. JAMA 1989; 262:914-919.
- Pennifer Erickson and Donald Patrick. Health Status and Health Policy 1993; Chapter 7, pp. 181-212.
- Ian McDowell and Claire Newell. Measuring Health – A Guide to Rating Scales and Questionnaires 2<sup>nd</sup> Edition 1996, Chapter 10, pp.494-497.

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**February 10, 2003 (Week 6):**

**A: Prostate Cancer and HRQOL (Litwin)**

**B: Neurologic Disease and HRQOL (Vickrey)**

Required Readings

*Part A:*

Litwin MS, Hays RD, Fink A, Ganz PA, Leake B, Leach GE, Brook RH. Quality of life outcomes in men treated for localized prostate cancer. JAMA 1995;273:129-135.

*Part B:*

Vickrey BG, Hays RD, Engel J, Spritzer K, Rogers WH, Rausch R, Graber J, Brook RH. Outcome assessment for epilepsy surgery: The impact of measuring health-related quality of life. Ann Neurol 1995;37:158-166.

References

*Part B:*

- Deyo RA; Diehr P; Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. Controlled Clinical Trials, 1991 Aug, 12(4 Suppl):142S-158S.
- Sneeuw KCA, Aaronson NK, de Haan RJ, Limburg M. Assessing quality of life after stroke: The value and limitations of proxy ratings. Stroke 1997;28:1541-1549.
- Vickrey BG, Hays RD, Graber j, et al. A health-related quality of life instrument for patients evaluated for epilepsy surgery. Medical Care, 1992;30:299-319.

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**February 17, 2003 (Holiday, Week 7)**

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**February 24, 2003 (Week 8)**

**A: HRQOL Preference Measures (Hays)**

**B: HRQOL in HIV/AIDS and HRQOL (Cunningham)**

Required Readings

*Part A:*

Kane, pp. 35-48.

Bowling, pp.14-15

Bennett, K. J., & Torrance, G. W. Measuring health state preferences and utilities: Rating scale, time trade-off, and standard gamble techniques. In *Quality of Life and Pharmacoeconomics in Clinical Trials*. Spilker B, ed. Philadelphia: Lippincott-Raven Publishers 1996; Chapter 27, pgs. 253-265.

*Part B:*

Cunningham WE, Hays RD, Ettl MK, Dixon WJ, Beck CK, Shapiro MF. The prospective effect of access to medical care on health-related quality of life outcomes in patients with symptomatic HIV disease. *Medical Care*. 1998;36(3):295-306.

Hays RD, Cunningham WE, Sherbourne CD, et al. Health-related quality of life in patients with Human Immunodeficiency virus Infection in the United States: Results from the HIV Costs and Services Utilization Study. *American Journal of Medicine* 2000;108:714-722.

References

*Part A:*

- Hays RD, Alonso J, Coons SJ. Possibilities for summarizing health-related quality of life when using a profile instrument. In M. Staquet, R. Hays & P. Fayers (eds.) Quality of Life Assessment in Clinical Trials: Methods and Practice. Oxford: Oxford University Press. 1998; pgs. 143-153.
- Feeny G, Torrance GW, Furlong WJ. Health Utilities Index. In *Quality of Life and Pharmacoeconomics in Clinical Trials*. Spilker B, ed. Philadelphia: Lippincott-Raven Publishers; 1996;Chapter 26, pgs 239-252
- Kaplan RM. Health Outcome Models for Policy Analysis. *Health Psychology* 1989; 8:723-735.
- Kind P. The EuroQol Instrument: An Index of Health-Related Quality of Life. In *Quality of Life and Pharmacoeconomics in Clinical Trials*. Spilker B, ed. Philadelphia: Lippincott-Raven Publishers, 1996;Chapter 22, pgs. 191-202.
- McNeil BJ, Weichselbaum R, Pauker SG. Speech and Survival: Tradeoffs between quality and quantity of life in laryngeal cancer. *NEJM* 1981; 305:982-87.

- Revicki DA, and Kaplan RM. The relationship between psychometric and utility-based approaches to the measurement of HRQOL.; *Quality of Life Research* 2;1993:477-487.
- Tsevat, J, Cook EF, Green ML, et al. Health values of the seriously ill. SUPPORT investigators. *Annals of Internal Medicine*, 1995;122(7):514-20.

### *Part B*

- Cleary PD, Fowler FJ, Weissman J, et al. Health-related quality of life in persons with acquired immune deficiency syndrome. *Med. Care* 1993; 31:569-580.
- Cunningham WE, Bozzette SA, Hays RD, Kanouse DE, Shapiro MF. Comparison of health-related quality of life in clinical trial and non-clinical trial HIV infected cohorts. *Medical Care*, April 1987.
- Schag, Ganz, Kahn, and Petersen. Assessing the needs and quality of life of patients with HIV infection: development of the HIV overview of Problems-Evaluation System ( HOPES ). *Qual Life Res.* 1992 ; 1:397-413
- Wu AW, Hays RD Kelly S Malitz KF Bozzette SA. Applications of the medical outcomes study health-related quality of life measures in HIV/AIDS. *Quality of Life Research.* 1997; 6:531-554.

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## **March 3, 2003 (Week 9)**

### **A: Minimally Important Differences/Responsiveness to Change (Hays)**

### **B: Cancer, Lung Cancer, and HRQOL (Sarna)**

#### Required Readings

##### *Part A:*

Hays RD, and Woolley JM. The Concept of Clinically Meaningful Difference in Health Related Quality of Life Research: How Meaningful Is It? *Pharmacoeconomics* 2000; 18(5): 419-423.

##### *Part B:*

Sarna, L.; Padilla, G.; Holmes, C.; Tashkin, D.; Brecht, M. L., and Evangelista, L. Quality of life of long-term survivors of non-small-cell lung cancer. *J Clin Oncol.* 2002 Jul 1; 20(13):2920-9.

#### References

##### *Part A:*

- Bindman AB, Keane D, Lurie N. Measuring health changes among severely ill patients: the floor phenomenon. *Medical Care* 1990; 28(12):1142-1152.
- Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. *J Chronic Disease* 1987;4(2):171-178.
- Hays RD and Hadorn D. Responsiveness to change: An aspect of validity, not a separate dimension. (Editorial) *Quality of Life Research* 1992; 2:73-76.

- Kazis LE, Anderson JJ, Meenam RF. Effect sizes for interpreting changes in health status. *Medical Care*. 1989;27:S178-189.
- Sprangers M and Aaronson N. The role of health care providers and significant others in evaluating the quality of life of patients with chronic disease: a review. *Clin Epidemiol* 1992; 45 (7): 743-760.
- Weinberger M, Oddone EZ, Samsa GP, Landsman PB. Are health-related quality of life measures affected by the mode of administration? *J Clin Epidemiol*. 1996;49:135-140.

*Part B:*

- Ganz PA, Schag CAC, Lee JJ, et al. Breast conservation versus mastectomy. Is there a difference in psychological adjustment or quality of life in the year after surgery? *Cancer* 1992; 69:1729-1738.
- Coates A, GebSKI V, Bishop JF, et al. Improving the quality of life during chemotherapy for advanced breast cancer. *NEJM* 1987; 317:1490-5.
- Ganz PA, Hirji K, Sim M-S, et al. Predicting psychosocial risk in patients with breast cancer. *Med Care* 1993; 31:419-431.

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**March 10, 2003 (Week 10)**

**A: Applicability of Generic Measures to Persons with Disabilities (Hays)**

**B: Outcomes and Effectiveness Research in HIV/AIDS (Cunningham)**

Required Readings

*Part A:*

Hays, R. D.; Hahn, H., and Marshall, G. Use of the SF-36 and other health-related quality of life measures to assess persons with disabilities. *Arch Phys Med Rehabil*. 2002 Dec; 83(12 Pt 2):S4-S9.  
(Abstract included, final manuscript to be handed out)

*Part B:*

Staquet MJ, Berzon RA, Osoba D, Machin D. Guidelines for reporting results of quality of life assessments in clinical trials. *Quality of Life Assessment in Clinical Trials* 1998;337-347.

References

- Paltiel DA and Stinnett AA. *AIDS. Quality of Life and Pharmacoeconomics in Clinical Trials*, 2<sup>nd</sup> Edition 1996; 1053-1062.

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**March 14, 2003 (Week 11)**

Papers Due (Friday before Final exams week)